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AMENDMENT UNDER 37 C.F.R. 1.116
EXPEDITED PROSEUCTION
ART UNIT 1648

8/23/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	John B. Harley, Judith A. James, and Kenneth M. Kaufman		
Serial No:	09/500,904	Art Unit:	1648
Filed:	February 9, 2000	Examiner:	Foley, S.

For: DIAGNOSTICS AND THERAPY OF EPSTEIN-BARR VIRUS IN AUTOIMMUNE DISORDERS

Commissioner for Patents
Washington, D. C. 20231

AMENDMENT

Sir:

The following comments are in response to the Office Action mailed May 8, 2002.

Comments regarding the Figures and Specification

It appears from the office action that the Response to Notice of Non-Compliant Amendment filed by facsimile on December 7, 2001, did not match with this application (although it appears from the decision withdrawing the abandonment that it did). Another copy is enclosed, along with proof of facsimile transmission. This amendment cancelled the references to Figures 9-11 at pages 10-11 in the specification, cancelled the reference to Figure 9 on page 61, the reference to Figure 10 on page 64, and the reference to Figure 11 on page 65. Formal drawings of Figures 1-8 were mailed today, August 8, 2002.

Double Patenting Rejection

A terminal disclaimer will be found when claims are otherwise allowable.

Rejections under 35 U.S.C. 112

Claims 6-10 and 19-22 were rejected under 35 U.S.C. 112, second paragraph, as indefinite, and under 112, first paragraph, as not enabled. These rejections are respectfully traversed. To the extent the undersigned can understand the rejection of claims 6-10 and 19-22 as indefinite, it appears it is based on the examiner's position that the terms in the claims are relative and result in no more than probabilities.

Claim 1 recites:

A diagnostic test to predict the risk of developing lupus comprising

(1) reagents which can be used to detect levels of antibodies to Epstein-Barr virus, indicators of Epstein-Barr infection of cells, or levels of Epstein-Barr DNA or protein in a patient, and

(2) control samples from individuals not at risk of developing lupus, and

(3) means for determining the differences in levels of a patient and control samples to distinguish individuals at higher risk of developing lupus from those at lower risk of developing lupus.

Those skilled in the art would have no trouble interpreting this claim. It represents a very standard assay, although the specific (rather than general) reagents and desired goal are not typical.

The test contains reagents such as antibodies to EBV antibodies, EBV proteins, or proteins which are known indicators of EBV infection; control samples which are used to eliminate "background" reactions with the reagents not indicative of developing lupus; and means for distinguishing the background reactions (i.e., the reactions between the reagents and

the control samples) and the patient samples. If the reaction is greater with the patient sample than with the controls, the patient is at risk. The means are standard - in some cases, the means may be an ELISA assay, where a colored reaction is titered to quantitate the number of reactants; it may be a chromatographic assay where a spectrophotometer is used to measure the intensity of the reaction; it may be an immunoprecipitation assay; This is certainly a relative analysis, but one commonly practiced by those skilled in the art. Who has not had a blood analysis in which each determination is followed by the normal range, so that one can determine whether one is within the normal range or outside the normal range, and therefore at a great risk?

Claims 6-10 and 19-22 have been rejected apparently for use of the term "likelihood" and "at risk". Contrary to the statement that one would not know what this means, the terms are well known to those skilled in the art. Particularly in a case such as lupus, where there is a genetic component (same as in some types of cancer or heart disease), there are tests that can be performed to indicate if an individual is more likely than the average individual to develop a disorder, in this case, lupus. It is now well established that those individuals with elevated titers to Epstein-Barr virus are at greater risk of developing Burkitt's lymphoma and nasopharyngeal carcinoma (see page 2, first paragraph, and references cited therein).

Contrary to the examiner's assertion that a cause-and-effect must be established between EBV and lupus before one can claim an assay, this is not the legal standard. The test is whether or not the test yields a more probable than not outcome - which is all many physicians require before initiating far more expensive and comprehensive testing which would be more definitive.

However, three abstracts are enclosed which provide evidence that EBV infection is at a minimum correlated with lupus:

Verdolini, et al., Br. J. Dermatol. 146(5):877-881(2002)

Dror, et al. Am. J. Kidney Dis. 32(5):825-828 (1998)

James, et al., Arthritis Rheum. 44(5):1122-1126 (2001)

The requirement under 35 U.S.C. is that the application must enable one skilled in the art how to make and use that which is claimed. The examiner is entitled to doubt the truth of what has been claimed, but has failed to identify why one skilled in the art would not be able to practice an assay as claimed. The evidence with this response shows that those skilled in the art recognize the association between EBV and lupus.

Allowance of claims 6-11 and 19-22 is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this , along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: August 8, 2002

Patrea Pabst